No. 20-

IN THE

Supreme Court of the United States

FUSION IV PHARMACEUTICALS, INC.
DBA AXIA PHARMACEUTICAL,
AND NAVID VAHEDI, PHARM D.,

Petitioners,

v.

ANNE SODERGREN IN HER OFFICIAL CAPACITY
AS INTERIM EXECUTIVE OFFICER FOR THE
CALIFORNIA STATE BOARD OF PHARMACY;
AND DOES 1 THROUGH 10, INCLUSIVE,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

AL MOHAJERIAN
Counsel of Record
ANN ANOOSHIAN
MOHAJERIAN, APLC
1901 Avenue of the Stars, Suite 1100
Los Angeles, CA 90067
(310) 556-3800
al@mohajerian.com

Counsel for Petitioners

302507

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED FOR REVIEW

Whether 21 U.S.C. §353b of the Federal Food, Drug and Cosmetic Act "FDCA" (the "Compounding Quality Act" which is part of the "Drug Quality and Security Act"), enacted in 2013 which itself "created" federal outsourcing facilities and provided for their oversight by the federal government, preempts California state law licensing requirements contained in Business and Professions Code §4129 and §4129.1, which attempt to require licensing and regulation by the state of California?

Whether 21 U.S.C. §353b of the FDCA preempts California state laws and regulations (Business and Professions Code §4129 and §4129.1) in addition to licensing requirements for federal outsourcing facilities?

Whether California law imposing licensing requirements and regulations (Business and Professions Code §4129 and §4129.1) violates the United States Commerce Clause in light of 21 U.S.C. §353b of the FDCA, the purpose of which was to create and provide oversight of federal outsourcing facilities which are the sole means of placing compounded medications and drugs into interstate commerce in the case of a shortage or in the case of a clinical necessity?

Whether the FDCA's preemption of enforcement (21 U.S.C. §337) of federal outsourcing facilities created under 21 U.S.C. §353b, extends to and thus preempts state laws which require additional licensing and/or regulation of federal outsourcing facilities?

PARTIES TO THE PROCEEDING

Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical

Navid Vahedi, Pharm. D.

California State Board of Pharmacy, Acting Executive Director

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, Petitioner Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical states that it is an incorporated entity under the laws of California, that it has no parent company, and that no publicly held company owns ten percent (10%) or more of stock relating to it.

Petitioner Navid Vahedi, Pharm D. states that he is an unincorporated private citizen, that he has no parent company, and that no publicly held company owns ten percent (10%) or more of stock relating to him.

RELATED CASE STATEMENT

Fusion IV Pharmaceuticals, Inc et al. v. Executive Director Virginia Herold, et al., 2:19-cv-01127-PA-FFM, United States District Court Central District of California; Judgment entered June 21, 2019.

Fusion IV Pharmaceuticals, Inc dba Axia Pharmaceutical, a California corporation; Navid Vahedi, Pharm D. v. Ann Sodergren, in her Official Capacity as the Interim Executive Officer of the California State Board of Pharmacy, 19-55791, United District Court of Appeals for the Ninth District, Judgment entered July 29, 2020.

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OPINIONS BELOW

The opinion of the District Court in case number 2:19-cv-01127-PA-FFM dated June 21, 2019 was dismissed with prejudice Petitioners' lawsuit, and is reproduced at Appendix I. The opinion of the Ninth Circuit in case number 19-55791 dated June 17, 2020 is reproduced at Appendix II. The order of the Ninth Circuit denying *en banc* hearing by the full court dated July 29, 2020 is reproduced at Appendix III.

JURISDICTIONAL STATEMENT

This Court has jurisdiction pursuant to 28 U.S.C. §1254(1) as the final judgment of the Ninth Circuit is subject to review by this Court on a writ of certiorari. This court has jurisdiction as the appeal arises from the Ninth Circuit's decision and involves constitutional questions of federal preemption of federal outsourcing facilities created under 21 U.S.C. §353b, and violation of the United States' Commerce Clause.

Petitioners seek review on this writ for the following reasons pursuant to Rule 10 of this Supreme Court: (a) a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter; has decided an important federal question in a way that conflicts with a decision by a state court of last resort; or has so far departed from the accepted and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for an exercise of this Court's supervisory power (Rule 10 (a)); and a state court or a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by

this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court (Rule 10 (c)).

The Court has jurisdiction because this appeal is timely, as the Ninth Circuit decision was filed on June 17, 2020; and the Ninth Circuit refusal for en banc hearing was filed on July 29, 2020. This appeal was filed online, on December 16, 2020. This Court requested corrections, which are due on or before March 8, 2021.

CONSTITUTIONAL PROVISIONS AND FEDERAL STATUTES

UNITED STATES CONSTITUTION SUPREMACY CLAUSE ARTICLE VI CLAUSE 2

UNITED STATES COMMERCE CLAUSE ARTICLE I § 8 CLAUSE 3

21 U.S.C. §353b Title 21 Federal Food, Drug and Cosmetic Act "FDCA"

21 U.S.C. §336

21 U.S.C. §337(a) Title 21 FDCA

21 U.S.C. §353a Title 21 FDCA

21 U.S.C. §371 Title 21 FDCA

21 U.S.C. §379a Title 21 FDCA

21 U.S.C. §379j-62 Title 21 FDCA

Cal Bus & Prof. Code 4129

Cal Bus & Prof. Code 4129.1

Cal Bus & Prof. Code 4129.4

STATEMENT OF THE CASE

Petitioners Fusion IV Pharmaceuticals, Inc dba Axia Pharmaceutical (hereinafter referenced as "Fusion IV") and Navid Vahedi, Pharm.D. (hereinafter referenced as "Vahedi"), collectively "Petitioners", appeal from the judgment of the Ninth Circuit Court of Appeal (entered on June 16, 2020) in the case of Fusion IV Pharmaceuticals, Inc dba Axia Pharmaceutical and Navid Vahedi, Pharm D. v. Anne Sodergren in Her Official Capacity as Interim Executive Officer for the California State Board of Pharmacy ("Respondent") Ninth Circuit Case No. 19-55791. A request for an *en banc* hearing was filed by Petitioners (denied this request July 29, 2020).

Fusion IV is a federal outsourcing facility, created by Congress in 2013 and registered pursuant to federal enabling statute 21 U.S.C. §353b, the Compounding Quality Act, enacted in 2013. This statute was added to Title 21 of the Food, Drug and Cosmetic Act "FDCA", Title 21 Chapter 9. §353b is part of the "Drug Quality and Security Act" which consisted of Title I "Compounding Quality Act", creating federal outsourcing facilities and removing mass-compounding from "state licensed pharmacies" entirely (relevant to this petition) and Title II "Drug Supply Chain Security", removing all drug tracing from states.

In the same instrument where Congress enacted 21 U.S.C. §353b, it also amended 21 U.S.C. §353a to limit state licensed pharmacies to compounding only pursuant to a physician's prescription and in limited amounts. See, 21 U.S.C. §353a. This amendment required submissions from state boards of pharmacy: "The Secretary shall receive submissions from State boards of pharmacy (1) describing actions taken against compounding pharmacies, as described in subsection (b) or (2) expressing concerns that a compounding pharmacy may be acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a)".

For state licensed pharmacies, Congress explained how a state may proceed: (1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding. (2) The suspension or revocation of a State-issued pharmacy license or registration for violations of a State's pharmacy regulations pertaining to compounding. (3) The recall of a compounded drug due to concerns relating to the quality or purity of such drug." No such language exists in §353b.

These FDCA provisions refer to outsourcing facilities as "federal facilities" as opposed to state licensed pharmacies. See, 21 U.S.C. §353a. §353a(a) provides in pertinent part: "Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription … and if the compounding … is by … a licensed pharmacist in a State licensed pharmacy **or a Federal facility**, or … a licensed physician ...". *21 U.S.C. §353a emphasis added.*

Fusion IV began operations on or about January 6, 2017 after registering with the United States Food and Drug Administration ("FDA") pursuant to 21 U.S.C. §353b. Four years after Congress enacted the federal statute, California enacted Bus. & Prof. Code 4129 and 4129.1, which defined an outsourcing facility as one licensed by the state of California, required state licensing by the Board of Pharmacy, investigation by the Board of Pharmacy, oversight by the Board of Pharmacy, review of twelve months of records and additional requirements, prior to an outsourcing facility doing business in California. It was at this point that California violated the Supremacy Clause and through its enforcement violated the Commerce Clause. Fusion IV did apply for a California license which was denied in 2017.

In 2018, Petitioners filed a lawsuit in district court, *Fusion IV Pharmaceuticals, Inc v. Xavier Becerra et al. case number 2:18-cv-02561-PA-FFM.* Judge Percy Anderson did not consider the preemption issues but dismissed this matter without prejudice on July 17, 2018 stating that Petitioners' had not exhausted their "administrative remedies". In 2019, Fusion IV filed a second lawsuit alleging violation of due process and federal preemption, again landing before Hon. Percy Anderson. *Fusion IV Pharmaceuticals Inc v. Anne Sodergren in her official capacity, case number 2:19-CV-01127-PA-FFMx.* Judge Anderson dismissed the matter with prejudice on June 21, 2019 without entertaining oral argument/further briefing, after granting a cross-motion for judgment on the pleadings filed by the Board of Pharmacy. The district court further ordered costs incurred by the Board to be paid by Petitioners. Petitioners appealed each and every holding of the district court's June 21, 2019 decision. The Ninth Circuit affirmed the district court judgment in

a four-page opinion on June 16, 2020 in the case of *Fusion IV Pharmaceuticals, Inc dba Axia Pharmaceutical and Navid Vahedi, Pharm D. v Anne Sodergren in Her Official Capacity as Interim Executive Officer for the California State Board of Pharmacy*, Ninth Circuit Case No. 19-55791. In a unanimous decision the Ninth Circuit affirmed the district court judge's ruling, which had adopted the language of the Board of Pharmacy's brief (errors too). The Ninth Circuit in affirming the District Court, also requires Petitioners to pay the costs of Respondent. This order is also appealed. The Ninth Circuit panel included Ninth Circuit Judges Johnnie B. Rawlinson and N.R. Smith, and District Court Judge Edward R. Korman of the Eastern District of New York. Petitioner's filed a request for an *en banc* review. This was denied on July 29, 2020. Petitioners appeal from the judgment of the Ninth Circuit Court of Appeal and order awarding costs of suit.

REASONS FOR GRANTING THIS WRIT

1. Express preemption is clear in the language of the federal statute which created "outsourcing facilities" (the FDCA refers to these as "federal facilities" as opposed to "state licensed pharmacies"). Federal law defines what a federal outsourcing facility is: in order to become an outsourcing facility, it must register with the federal government; and the drug must be compounded in an outsourcing facility "in which the compounding of drugs occurs only in accordance with this section". 21 U.S.C. §353b(a)(11). Such language is repeated throughout this section of the FDCA.

2. California Bus. & Prof. Code §4129 and §4129.1 violate the Supremacy Clause as this state law redefines an

"outsourcing facility" as one having been licensed and regulated by the State of California.

3. The decision by the Ninth Circuit is in conflict with decisions of this Supreme Court in *Kansas v. Garcia* decided March 3, 2020 which held "if federal law imposes restrictions or confers rights on private actors and a state law confers rights or imposes restrictions that conflict with the federal law, the federal law takes precedence and the state law is preempted". *U.S. Const.* art. 6, cl. 2; *Kansas v. Garcia* (2020) 140 S. Ct 791 (and *Sperry v. Florida* (1963) 373 U.S. 379, *Douglas v. SeaCoast Products, Inc.* (1977) 431 U.S. 265; *Pennsylvania v. Wheeling & Belmont Bridge* Co. (1852) 54 U.S. 518, 566).

4. Pursuant to FDCA 21 U.S.C. §379a: "In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist."

5. Pursuant to FDCA 21 U.S.C. §371: "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary." California law and the Ninth Circuit's decision regarding preemption are in direct opposition to §371 which reserves 'enforcement' (of an FDCA-created facility) to the United States. The FDCA is viewed as a whole. *FDA v. Brown & Williamson* (2000) 529 U.S. 120.

6. The Ninth Circuit decision cited language not contained in the statute to the effect that in

quotation marks that the "DQSA clearly allows for complementary state regulation[s]", which is nowhere to be found in the text of the statute applicable to outsourcing facilities or state-licensed pharmacies, or any FDA guidance materials.

7. The Ninth Circuit disregarded the language of the statute, the FDCA, or the amendment to FDCA §353a - which *did* provide for state involvement of 'state licensed pharmacies', the single allowance in §353b which gave states continuing permission to collect fees for a 'pharmacy' if one was present in the federal facility. The Ninth Circuit disregarded the preemptive language in the statute requiring action by the Secretary of the Department of Health and Human Services (with 182 instances of 'the Secretary shall'); the language regarding inspection mandate, training of inspectors and fees imposed by the Secretary to cover exclusively the oversight of outsourcing facilities; the detailed requirements of containers/labels; exemptions for outsourcing facilities; and mandated FDA reports/guidance which state that the FDA does not plan to 'take action' or enforce a provisionary mandate (binding precedent holds this enforcement by the federal government preempts state 'enforcement').

8. The Ninth Circuit held California licensing requirements do not violate the "dormant" commerce clause principles. However, where a federal statute exists, "dormant" commerce clause analysis is an incorrect analysis and thus the Ninth Circuit decision goes against binding Supreme Court precedent stating this principle of construction. Any measures

which frustrate the purpose of Congress violate the commerce clause.

9. The Ninth Circuit stated that because there was no "separate preemption clause" in the federal statute, there could be no preemption. This goes against binding Supreme Court precedent which allows preemption to be found if the language of the statute provides for enforcement and oversight by the federal government exclusively, such as language providing for "only in compliance with this" statute.

10. The Ninth Circuit decision, finding that there was no pervasive "scheme of federal regulation", was clear error and goes against binding Supreme Court precedent such as *Hines v. Davidowitz* (1941) 312 U.S. 52. There is evidence of congressional intent in multiple bills introduced by Congress, after quite a number of incidents and a final tragic incident resulting from one state placing adulterated compounds into interstate commerce; committee reports; full chamber hearings reflecting intent to provide exclusive oversight. In 2013 Congress enacted 21 U.S.C. 353b, overhauling the entire field of mass compounding which was redrawn into a federally supervised system with federal standards - current Good Manufacturing Practices (CGMP).

11. The Ninth Circuit erroneously stated California law does not "conflict" with the federal statute because a California license only requires a federal license. This is not true or accurate. By its very existence California law frustrates the federal right to conduct business as a federal outsourcing facility. California

law redefines what an outsourcing facility is and causes the entire authority of the federal statute to become dependent upon the state of California's determination, inspection, opinion, review, oversight, regulation, discipline[1], fee requirements, and decision.

12. California law and the Ninth Circuit decision conflict with the 'discretionary regulation process' of the FDCA, which provides in 21 U.S.C. §336: "Nothing in this Act shall be construed as requiring the FDA to report for prosecution minor violations of this Act whenever it believes that the public interest will be adequately served by a suitable written notice or warning." According to the FDCA, the FDA has an explicit grant of discretionary authority, whereas California law provides that it alone defines what an outsourcing facility is, in California and outside of California as well, and that California regulations are to be followed[1], resulting in an outsourcing facility to be subject to California licensing, regulations and discipline which differ from published FDA guidance/ rules.

13. The Ninth Circuit opinion conflicts with the following: the FDCA provides in 21 U.S.C. §337a: "proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." According to §337a, a state may not 'enforce' this Act. Enforcement necessary includes the licensing requirements of an entity created under the FDCA. As provided for in 21 U.S.C. §336, the FDCA may choose to not pursue prosecution of injunction for

1. Bus & Prof Code 4129.1.and 4129.4

minor violations of this chapter whenever it believes that the public interest will be adequately served by a suitable written notice or warning.

14. Notably in 21 U.S.C. §337a, subsection (b) provides that a "State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State. The failure to include 21 U.S.C. §353b is instructive as to the FDCA's intent to preempt state enforcement.

15. The Ninth Circuit opinion contradicted its own decision in 2019 which held that California law was impliedly if not expressly preempted by the FDCA because of the FDCA's 'discretionary enforcement process'. In *Borchenko v. L'Oreal USA, Inc.,* involving the California's Sherman Food, Drug, and Cosmetic Law, which mirrored the FDCA, the court held state "claims" were impliedly preempted by the FDA where the "claim" existed solely by virtue of the FDCA and sought to enforce provisions of the FDCA, because it conflicted with the FDCA discretionary enforcement process. *Borchenko v. L'Oreal USA, Inc.* (C.D.Cal.2019) 389 F.Supp.3d 769 (emphasis added). Although the law in question in *Borchenko* 'mirrored' FDCA language, it still was found to be preempted. Bus. & Prof. Code §4129 *et seq* does not mirror at all federal law but redefines and attempts to 'trump' federal law.

16. The Ninth Circuit opinion conflicts with FDCA language requiring inspections of outsourcing

facilities to be done by accredited inspectors chosen by the facility. See, 21 U.S.C. §374(g)(1). Conflicting California law requires inspections and approval pursuant to Bus. & Prof. Code §4129.1 and by state 'personnel' who are not required to be accredited and are not chosen by the facility for its annual or interim inspections (with such inspection fees to be paid to the Secretary).

17. The Ninth Circuit's decision conflicts with the language of FDCA 21 U.S.C. §379a: The FDCA has statutorily created a presumption of existence of jurisdiction and a connection with interstate commerce. In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist." The Ninth Circuit held that Petitioners had not established that California law touched at all upon interstate commerce.

18. FDCA expressly reserved authority to enforce the operation of outsourcing facilities and thus preempts state enforcement. Enforcement necessarily includes 'licensing' and regulation. Publications by the FDA have indeed cautioned states to not legislate in conflict with the federal law.

19. This petition presents important federal questions as California and other states remain in conflict and frustrate the purpose of the Compounding Quality Act in 21 U.S.C. §353b.

20. The health and welfare of the citizens of the United States is affected to a great extent by the confusion

created by disparate state regulation of federal outsourcing facilities which was the reason Congress enacted the federal statute.

21. Federal outsourcing facilities are the exclusive means of placing compounded medications into interstate commerce in the event of a "shortage" of FDA approved pharmaceutical drugs, or for a clinical need for such compounds, and in the event of a national emergency.

SUMMARY OF ARGUMENT

This matter presents the question of whether 21 U.S.C. §353b known as the "Compounding Quality Act" (part of the "Drug Quality and Security Act" enacted in 2013 and now a part of the FDCA) preempts California law, specifically Business and Professions Code §4129, §4129.1 and §4129.4- which is specifically preempted by the language of the statute, directly conflicts with 21 U.S.C. §353b and the FDCA, and frustrates a federal statutory 'right' to engage in the business of an outsourcing facility. This matter also presents the question of whether California law violates the U.S. Constitution's Commerce Clause.

The FDCA itself provides for preemption. The authority to promulgate regulations for the enforcement of the FDCA ... is vested in the Secretary. 21 U.S.C. §337a. Hearings authorized or required ... shall be conducted by the Secretary or such officer or employee as he may designate for the purpose. 21 U.S.C. §337a .

21 U.S.C. §353b created "federal outsourcing facilities", which are "federal" facilities (see 21 U.S.C.

§353a) and are the only vehicles to mass-compound drugs/medications, where there is a shortage of FDA approved medications or a clinical need, to be placed in interstate commerce.

Prior to 21 U.S.C. §353b, state licensed pharmacies accomplished the mass-compounding without limit, with varying state requirements and oversight, and very little if any federal oversight. This "confusion" and resultant poor quality of compounds led to a large number of illnesses and deaths due to tainted compounds being distributed through interstate commerce.

A 2012 meningitis incident wherein sixty-four Americans died and many hundreds/thousands more became severely ill, leading Congress to consider multiple bills, hold hearings, enacted 21 U.S.C. §353b as part of the FDCA, and also enacted drug tracing legislation. Congress also simultaneously amended former 21 U.S.C. §503 which became §353a, creating federal oversight for state licensed pharmacies which thereafter were forbidden to compound mass quantities and were limited to compounding for identified patients, pursuant to state law and licensing.

21 U.S.C. §353b "created" outsourcing facilities and a federal FDA oversight plan at the direction of the Secretary of the Department of Health and Human Services. Pursuant to this enabling statute, outsourcing facilities were to register with the federal government, comply with all current Good Manufacturing Practices, undergo investigations and audits by federal employees, and operate according to the strictures of 21 U.S.C. §353b and guidelines proposed by the FDA which also

provided for discretionary oversight and regulation. Indeed, the statute provides for specific preemption and exclusivity: "Outsourcing facility requirement: The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section". §353b(a)(11) emphasis added.

Within this statute is no mention of state licensing or oversight (unlike 21 U.S.C. §353a relative to state licensed pharmacies). The only permission given the states in §353b is to collect 'fees' for a state licensed pharmacy, if such is located within the same structure as the outsourcing facility.

California enacted legislation four years later in 2017 which required a federal outsourcing facility apply for and be granted a state license by the Board of Pharmacy prior to doing business in California. Cal. Bus. & Prof. Code §4129, and §4129.1. Outsourcing facilities are also subject to California regulations, inspections, fees and discipline including cessation of business and arrest. Bus. & Prof. Code §4129 redefines "outsourcing facility" as one that is licensed in California.

Since 2013, a majority of states have created inconsistent legislation requiring licensing/oversight/regulation, which vary by each state, similar to how states operated prior to 21 U.S.C. §353b, thus creating a web of differing requirements among the various states and causing, again, extensive confusion as to the manner in which outsourcing facilities could place mass compounded medications (in the case of a shortage) into interstate commerce. The FDA realized this and cautioned states against legislation which conflicts with federal law.

Express preemption language is clear throughout §353b, which created outsourcing facilities. There are 182 instances which state the Secretary 'shall' act "An outsourcing facility is exempt from the requirements of FDA approval, directions for use on labels, and requirements for manufacturers, re-packagers, wholesalers, distributers and dispensers] "if: the drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section". 21 U.S.C. §353b(a)(11) emphasis added. The FDCA provides for the discretionary regulation and enforcement of outsourcing facilities. At the same time as 21 U.S.C. §353b was enacted, Congress added 21 U.S.C. §379j-62 which provides for the authority to assess and use outsourcing facility fees for oversight/inspection. The FDCA may not be 'enforced' by other than the United States. 21 U.S.C. §337(a).

The reason for Petitioners seeking a writ of certiorari and review by this Supreme Court is first, the Ninth Circuit's error and conflict with Supreme Court precedent and its own precedent as outlined above, and to resolve conflicting state regulations and licensing requirements. California law facially disallows outsourcing facilities to conduct business despite being approved and registered with the federal government.

The necessity of placing medications into interstate commerce remains a concern of national importance and national security to a certain extent. Outsourcing facilities are the only means of accomplishing this.

LEGAL AUTHORITIES FOR GRANTING THE WRIT

Petitioners ask this Court to review federal preemption of federal outsourcing facilities in 21 U.S.C. §353b. Mass compounding is regulated by the FDCA requiring compliance with federal current Good Manufacturing Practices "CGMP", and oversight is conducted by the FDA. FDCA enforcement expressly preempts any state laws relevant to 21 U.S.C. §353b pursuant to 21 U.S.C. §337(a). Enforcement of the FDCA (which created outsourcing facilities) is only to be brought by the United States. Further, pursuant to 21 U.S.C. §353b, the FDA is to publish guidance documents advising outsourcing facilities of its findings, and its intent to prosecute, or to not prosecute/investigate. This discretionary enforcement and prosecution of the FDCA and FDA has long been understood to preempt state law and enforcement (discussed herein). The language is very specific in 21 U.S.C. §353b(b). "In order to become an outsourcing facility .. a facility shall register with the Secretary ... And indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under §356e of this title during the subsequent calendar year" ("list" meaning a list of drugs which have been reported as in 'shortage'). This statute defines an outsourcing facility as "a facility at one geographical location or address that (i) is engage in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section". 21 U.S.C §353b(d)(4)(A).

I. EXPRESS PREEMPTIVE LANGUAGE IS IN 21 U.S.C. 353b WHICH THE NINTH COURT FAILED TO CONSIDER AS WELL AS THE OBVIOUS IMPLIED PREEMPTION

The Supremacy Clause, U.S. Const., Art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824) (Marshall, *713 C.J.). Congress is empowered to pre-empt state law by so stating in express terms. *Jones v. Rath Packing Co.* (1977) 430 U.S. 519, 525.

The Ninth Circuit in its opinion stated that because there was no separate preemption clause, that Congress did not intend to preempt state law. Petitioners contend that 21 U.S.C. §353b preempts state law due to express preemption found in the preemptive language and the enactment of 21 U.S.C §353a, and in the establishment of a federal right to engage in interstate commerce; language within the statute itself which provides for express preemption; FDCA express preemption in the enforcement of Title 21; lack of any mention of state involvement as compared to the language in 21 U.S.C. 353a enacted the same day relevant to state-licensed pharmacies; field and implied preemption as a result of congressional intent; the expansive scheme of 21 U.S.C. 353b in conjunction with the simultaneous enactment of related Acts and amendment of laws relating to 'state licensed pharmacies'; conflict preemption as a result of California law's requirement of a 'license' in disregard for the federal right; California's rewriting of the federal statute; California's frustration of the purpose of Congress to create federal facilities which formerly were regulated by states (resulting in death and illness over a period of

years and culminating in a 2012 meningitis outbreak); and laws which conflict with FDCA regulation through the FDA (who has published intent and guidance documents and advised states to refrain from enacting legislation which conflicts with federal law).

Although here there is preemptive language, there is also implied preemption gathered from the congressional record and actual life circumstance. Congressional intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation. *Rice v. Santa Fe Elevator Corp.* (1947) 331 U.S. 218, 230. Pre-emption of a whole field also will be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Ibid.*; see *Hines v. Davidowitz* (1941) 312 U.S. 52; *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.* (1985) 471 U.S. 707, 712–13. The Ninth Circuit decision flies in the face of all of the above cited decisions of this Court dating back to 1824.

II. EXPRESS PREEMPTION IS IN THE LANGUAGE OF THE STATUTE AND ENFORCEMENT PROVISIONS OF THE FDCA

21 U.S.C. §353b clearly provides the definition of what an outsourcing facility is: "Upon electing and in order to become an outsourcing facility .. a facility shall register with the Secretary …". §353b(b)(1). The federal law defines an outsourcing facility as "a facility that elects to register as an outsourcing facility if each of the following conditions

is met: The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b)" (§353b(a)(1)); and "drugs compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section." (§353b(a)(11)). The words "only in accordance with this section" is unquestionably preemptive language. California law in Bus. & Prof. Code §4129 and §4129.1 attempts to rewrite this federal statute to define an outsourcing facility as one which is licensed by the state of California.

21 U.S.C. §337 provides: "enforcement" shall be only before the United States. Long-standing precedent also finds 'express' preemption where authority to prosecute and investigate is granted by the FDCA to the FDA which has been codified in §377. The FDA has published a number of "guidance" documents which explicitly state the FDA does not intend to investigate or take action against outsourcing facilities for certain actions.

III. THE NINTH CIRCUIT DECISION IS IN CLEAR CONFLICT WITH DECISIONS BY THIS COURT WHICH HOLD A FEDERAL LICENSE OR RIGHT MAY NOT BE FRUSTRATED BY STATE LAW

California law redefines ""outsourcing facility" and causes the entire authority of the federal statute to become dependent upon the state of California's determination, inspection, opinion, review, oversight, regulation, discipline, fee requirements, and decision. The Ninth Circuit opinion contradicts long-standing Supreme Court precedent such as *Sperry v. Florida* its state law from interfering with a "license" or federal "right" to engage

in an activity. *Sperry v. Florida (1963) 373 U.S. 379.* Even stopping the preemption consideration at this point, one would find California law is preempted.

This Court reaffirmed this point of law in the 2020 case of *Kansas v. Garcia* (2020) 140 S. Ct 791 where it stated: "If federal law imposes restrictions or confers rights on private actors and a state law confers rights or imposes restrictions that conflict with the federal law, the federal law takes precedence and the state law is preempted" and "In all cases, the federal restrictions or rights that are said to conflict with, and therefore preempt, state law must stem from either the Constitution itself or a valid statute enacted by Congress". U.S. Const. art. 6, cl. 2.

The Ninth Circuit decision conflicts with its own decision affirming *Sperry v. Florida*, in a 2017 decision of *Nw. Immigrant Rights Project v. Sessions:* "It is well established that Congress may authorize agencies to regulate attorneys appearing before them." See *Sperry v. Florida* (1963) 373 U.S. 379. In such cases, 'a State may not enforce licensing requirements which, though valid in the absence of federal regulation, give the State's licensing board a virtual power of review over the federal determination that a person or agency is qualified and entitled to perform certain functions, or which impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress.'" *Nw. Immigrant Rights Project v. Sessions* (2017) No. C17-716 RAJ) U.S.Dist.LEXIS 118058, at *20 (citing *Sperry v. Florida* (1963) 373 U.S. 379). A state may not further create licensing requirements where a federal license has been granted. See, *Sperry v. Florida* (1963) 373 U.S. 379; *Pennsylvania v. Wheeling & Belmost*

Bridge Co. (1852) 54 U.S. 518; (denial of a state license) *Douglas v. SeaCoast Products, Inc.* (1977) 431 U.S. 265.

Longstanding Supreme Court precedent dictates that state laws may not "hinder or obstruct the free use of a license granted under an act of Congress," or impose additional licensing requirements that impede activity sanctioned by a federal license." *Pennsylvania v. Wheeling & Belmont Bridge* Co. (1852) 54 U.S. 518, 566 (emphasis added). A state agency may not enforce licensing requirements which give the State's licensing board a virtual power of review over the federal determination. *Sperry v. Florida* (1963) 373 U.S. 379, 385.

As California Bus. & Prof. Code §4129, §4129.1 and §4129.4 are written, an outsourcing facility is defined as one which has received a California 'license' and complied with a laundry list of California requirements/regulations. Thus, the federal 'right' to engage in interstate commerce is violated essentially by the mere existence of this state requirement. An ongoing violation has continued since January of 2017. Bus. & Prof. Code §4129 and §4129.1, violates the Supremacy clause, in that this state law redefines an "outsourcing facility" as one having been licensed and regulated by the state of California, regardless of its status as a registered outsourcing facility under the federal enabling statute 21 U.S.C. §353b.

IV. THE EFFECT ON INTERSTATE COMMERCE IS ESTABLISHED PURSUANT TO STATUTE AS WELL AS FACT

Pursuant to 21 US.C. §379a there is a presumption of interstate commerce connection: "In any action to enforce the requirements of this chapter respecting a device,

tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist." Emphasis added.

The Ninth Circuit's decision finding "no" violation of the "dormant" commerce clause (also an error), is in direct opposition to this federal statute and precedent set by the Supreme Court and ordinarily followed by all lower courts.

V. FDCA IS REGULATED BY THE SECRETARY AND STATE LAWS CONFLICTING WITH FEDERAL REGULATIONS ARE INVALID

Pursuant to 21 U.S.C. §371: "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary." This itself is express preemption and applies to the entire "chapter" including 21 U.S.C. §353b (Chapter 9).

This statute further provides for 'regulation' only by the Secretary and through mandated guidance documents published by the FDA: "The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration." 21 U.S.C. §371(h)(1)(A). Further, "although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate

from such guidance[s] without appropriate justification and supervisory concurrence." 21 U.S.C. §371(h)(1)(B). California law and the Ninth Circuit's decision are in direct opposition to this federal statute which reserves 'enforcement' and regulation of an FDCA created facility to the United States.

VI. THE LANGUAGE OF THE STATUTE EXPLICITLY LIMITS STATE CONTROL TO STATE LICENSED PHARMACIES

The Ninth Circuit decision is erroneous in its understanding of the federal statute which was made clear by its citing "decisive" language which is not contained in the statute, even placing such language in quotation marks: "the DQSA clearly allows for complementary state regulation[s]". These words are nowhere to be found in the text of the statute applicable to outsourcing facilities, or any related statute for that matter, and are not contained in any FDA publications/guidance.

The Ninth Circuit ignored all of the following: the clear language of the statute, the amendment to §353a which *did* provide for state involvement of 'state licensed pharmacies', the single allowance in §353b which gave states continuing permission to collect fees for a 'pharmacy' if one was present in the federal facility, the plethora of preemptive language in the statute requiring action by the Secretary of the Department of Health and Human Services (182 instances of 'the Secretary shall'), the detailed inspection mandate and training of inspectors, the detailed fee usage by the Secretary to cover exclusively the oversight of outsourcing facilities, the detailed requirements of 'containers' and labels

and exemptions for outsourcing facilities, and others quite visible in the statute itself including mandated FDA reports and guidance to provide instruction for the facilities, most of which are published with a clause advising that the FDA does not plan to 'take action' or enforce a provisionary mandate, pending a final rule.

VII. THE LANGUAGE OF THE STATUTE LIMITING STATE INVOLVEMENT IS CLEAR

Nowhere does 21 U.S.C. §353b contemplate state regulation or oversight, except for the single authorization to collect fees. If one examines the statute, it becomes apparent that 21 U.S.C. §353b does provide for state involvement in collecting fees if a pharmacy is present within an outsourcing facility. The Ninth Circuit did not discuss the federal statute's explicit language at all.

The federal law in question created outsourcing facilities (as opposed to §353a relating to 'state licensed pharmacies' - providing for extensive state involvement), referred to as 'federal' facilities. §353b has no language indicating state oversight is permissible (beyond 'fees'). The FDCA does reference 'state pharmacies' which is evidence that Congress intended to allow states to license the 'pharmacy' and collect those licensing fees, and to not license or collect fees relating to the outsourcing facility.

VIII. FIELD PREEMPTION IS CLEAR FROM THE STATUTORY LANGUAGE AND CONGRESSIONAL INTENT

In addition to the events leading to Congressional hearings and enactment of several Acts by Congress

in November of 2013, federal oversight is mandated by §353b. The words 'established by the Secretary' or mandating action by the 'Secretary' appears 182 times in the Compounding Quality Act, referencing the Secretary of HHS. Also, the United States' "constitutional structure does not permit a court to rewrite a statute that Congress has enacted." *Puerto Rico v. Franklin-California Tax-Free Trust* (2016) 136 S. Ct. 1938.

IX. THE 'DORMANT' COMMERCE CLAUSE IS AN INCORRECT ANALYSIS WHERE CONGRESS HAS ACTED

The Ninth Circuit decision adopted the erroneous analysis proffered by the Board of Pharmacy - that California licensing requirements do not violate the "dormant" Commerce Clause principles. However, where a federal statute and right/license exists, this "dormant commerce clause" analysis is inapplicable.

This case does not implicate the "dormant" Commerce Clause. The issue before the Court is a pure Commerce Clause analysis because where Congress has acted and legislated on the matter, the commerce clause is not 'dormant'. See, *Western & Southern Life Ins. v. State Board of California* (1981) 451 U.S. 648. Thus, a similar determination of Congressional intent/frustration of legislative purpose is necessary to determine a violation, as well as a factual inquiry as to whether compounded drugs are being restricted entirely from being placed into interstate commerce. The FDCA statutorily establishes interstate commerce, and the burden on interstate commerce is unquestionably affected because outsourcing facilities were created for this reason – to place compounded drugs into interstate commerce.

The Ninth Circuit erroneously stated California's licensing requirement and statutes "do not violate dormant Commerce Clause principles". *Memorandum page 4,* citing *Nat'l Ass'n of Optometrists & Opticians v. Harris* (a dormant commerce clause case). *Nat'l Ass'n of Optometrists & Opticians v. Harris* (2013) 682 F.3d 1144. Such precedent is not applicable here, as its concern was in weighing the burden on interstate commerce from laws absent any Congressional act. This sort of analysis is inappropriate and misplaced.

As a result of California laws, Fusion IV is unable to operate as an outsourcing facility in California, or any state requiring a California 'license', despite congressional authorization to do so. This is not a case where two competing private companies are bickering over the ability to "compete" in the sale of "goods". Outsourcing facilities place medications into interstate commerce. The 'burden' is clearly excessive in light of the congressional interest being "compelling" on a national level – which trumps the smaller, self-centered and conflicting states' interests (the "mess" of differing state interests/oversight was the reason for Congress' enactment of 21 U.S.C. 353b in 2013). The Ninth Circuit failed to consider the congressional interest in "uniformity" - also conflicting with this Court's binding precedent in *Hall v. DeCuir* (1877) 95 U. S. 485 and *Southern Pacific Co. v. Arizona* (1945) 325 U. S. 761.

X. CONGRESSIONAL INTENT TO DOMINATE THE FIELD AND REPLACE ALL STATE LAWS IS UNQUESTIONABLE

In 2013, Congress created outsourcing facilities to provide for placing sterile compounds into interstate

commerce. Congress limited state licensed pharmacies to physician prescriptions. Congress required outsourcing facilities to operate pursuant to a federal CGMP under the guidance of the FDCA/FDA.

The Ninth Circuit stated without explanation that the federal statute is not a pervasive "scheme of federal regulation". As with its "invented" language, likely the Court did not comprehend that Congress had created outsourcing facilities to overhaul and replace an incompetent dangerous web of state "pharmacies" engaged in mass- compounding. This is not a case where Congress merely imposed a "regulation" upon an already existing industry.

The Ninth Circuit's decision goes against binding Supreme Court precedent such as *Hines v. Davidowitz* (1941) 312 U.S. 52; *Hillsborough Cnty., Fla.* (1985) 471 U.S. 707, 714; affirmed by *Chae v. SLM Corp.* (9th Cir. 2010) 593 F.3d 936, 942. *In re Chrysler* (9th Circuit) held that "states are precluded from regulating conduct in a field that Congress ... has determined must be regulated by its exclusive governance; such preemption can be inferred from a framework of regulation so pervasive that Congress left no room for the states to supplement it ..." *In re Chrysler LLC (*2009) 576 F.3d 108 at 927. *Emphasis added.* Pre-emption of a whole field also will be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Hines v. Davidowitz* (1941) 312 U.S. 52. In *Pom Wonderful v. Coca-Cola*, this Court found the FDCA preempted California's conflicting laws: "Either [the state law claims] impose obligations identical to those in the

FDCA … or they impose obligations additional to those in the FDCA, in which case they are preempted". In *Pom Wonderful,* this Court found California was attempting to impose laws in addition to those of the FDCA, thus they were preempted. *Pom Wonderful LLC v. The Coca-Cola Company, et al.*, No. 2:08-cv-06237-SJO-FMO, Docket Entry 417 (C.D. Cal. Feb. 13, 2013).

21 U.S.C. §377 prohibits "enforcement" by other than the United States. The California licensing scheme attempts to add licensing, regulation and discipline requirements for outsourcing facilities which are preempted by the FDCA and 21 U.S.C. §377. As the Ninth Circuit 'cited' but did not do: "When confronted with a preemption statute, a court must "'identify the domain expressly pre-empted by that language.' [A court] use[s] the text of the provision, the surrounding statutory framework, and Congress's stated purposes in enacting the statute to determine the proper scope of an express preemption provision." *Chae v. SLM Corp.* (9th Cir. 2010) 593 F.3d 936, 942.

XI. THE FDCA HAS CREATED A DISCRETIONARY REGULATION AND ENFORCEMENT PROCESS WHICH EXPRESSLY PREEMPTS STATE LAW

California law and the Ninth Circuit decision conflict with the 'discretionary regulation process' of the FDCA, which provides in 21 U.S.C. §336: "Nothing in this Act shall be construed as requiring the FDA to report for prosecution . . . minor violations of this Act whenever it believes that the public interest will be adequately served by a suitable written notice or warning." According to

this provision of the FDCA, the FDA has an explicit grant of discretionary authority. California law provides that California defines what an outsourcing facility is, and California regulations are to be followed. As a result outsourcing facilities are unable to operate despite Congressional authorization.

XII. A STATUTE CREATED BY CONGRESS TO ADDRESS AND CARRY OUT THE EXECUTION OF THE DRUG QUALITY AND SECURITY ACT AND THE COMPOUNDING QUALITY ACT MAY NOT BE BURDENED BY CONFLICTING STATE LAW

In *McCulloch v. Maryland* and *Gibbons v. Ogden*, Chief Justice John Marshall stated that "the states have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by Congress." The FDCA provides in 21 U.S.C. §337a: "proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." Because the FDCA 'created' outsourcing facilities and has authorized the HHS Secretary to have oversight, provide guidance, and publish final rules, a state law which purports to 'bar' a facility entirely based on state(s) law(s) and then to have it subject to state regulation (conflicting with CGMP) is clearly invalid.

According to §337a, a state may not 'enforce' the FDCA. Enforcement necessarily includes the licensing requirements of an entity created under the FDCA. As Supreme Court precedent established, if an 'action' arises due to the existence of the FDCA, it is preempted.

Only the United States may enforce the FDCA. See, *Pom Wonderful, LLC v. Coca-Cola Co.* (2014) 573 U.S.102 (overturning Ninth Circuit Court). Under "prohibited acts" of the FDCA, the FDCA preempts state enforcement, including enforcement regarding the resale of a compounded drug that is labeled "not for resale" in accordance with §353b of this title, or the intentional falsification of a prescription, or "the failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title." 21 U.S.C.A. §331ccc (i.e., outsourcing facilities).

As provided for in 21 U.S.C. §336, the FDCA may choose to not pursue prosecution of injunction for minor violations whenever it believes that the public interest will be adequately served by a suitable written notice or warning. And as provided in 21 U.S.C. §337a (except as provided in subsection (b)), proceedings for enforcement, or to restrain violations, shall be by and in the name of the United States. Notably, subsection (b) provides that a "State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State. The failure to include 21 U.S.C. §353b is instructive as to the FDCA's intent to preempt state enforcement.

XIII. CALIFORNIA LAW IS IMPLIEDLY PREEMPTED DUE TO THE FDCA'S DISCRETIONARY ENFORCEMENT PROCESS WHICH THE NINTH COURT RECOGNIZED IN 2019

The Ninth Circuit contradicted its decision in 2019 holding that California law was impliedly if not expressly preempted by the FDCA because of the FDCA's 'discretionary enforcement process'. In *Borchenko v. L'Oreal USA, Inc.*, a California Unfair Competition Law claim alleging a cosmetics company manufactured, marketed, sold, and distributed products that made false representations. Consumers brought an action under the Sherman Act which mirrored the FDCA. The 9th Circuit held this law was impliedly preempted by the FDCA where the claim existed solely by virtue of FDCA and law referencing the FDCA (and sought to enforce provisions of the FDCA) thus conflicting with FDCA discretionary enforcement process. *Borchenko v. L'Oreal USA, Inc.* (C.D.Cal.2019) 389 F.Supp.3d 769. Emphasis added.

Although the state law in *Borchenko* 'mirrored' FDCA language it still was found to be preempted. The Ninth Circuit's opinion herein, where state law does not 'mirror' federal law, conflicts with its own precedent decided in the same year with the same FDCA discretionary enforcement at issue.

XIV. FDCA LANGUAGE REQUIRES FEDERAL ENFORCEMENT BY ACCREDITED INSPECTORS

The Ninth Circuit opinion conflicts with FDCA language requiring inspections of outsourcing facilities

by accredited inspectors chosen by the facility. Pursuant to 21 U.S.C. §374(g)(1): "The Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that compound ... The owner ... may ... select an accredited person to conduct such inspections." The Ninth Circuit and California law conflict with this, as California law requires inspections and approval pursuant to California regulation (§4129.1) and by state 'personnel' who are not required to be accredited and are not chosen by the facility (inspection fees to be paid to the Secretary).

XV. FDCA CREATED A STATUTORY PRESUMPTION THAT WHERE A DRUG IS PLACED INTO INTERSTATE COMMERCE, THE INTERSTATE COMMERCE CLAUSE IS AFFECTED

The Ninth Circuit's decision conflicts with the language of FDCA 21 U.S.C.A. §379a: The FDCA has statutorily created a presumption of existence of jurisdiction and a connection with interstate commerce. In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist."

The Ninth Circuit decision held that Petitioners had not established that California law touched at all upon interstate commerce. No further discussion was engaged in by the Ninth Circuit. Thus, the Ninth Circuit decision is in clear conflict with federal statutory authority and contradicts this federal statutory presumption. Thus, a factual inquiry as to whether compounded drugs are

being restricted entirely from being placed into interstate commerce is necessary. Here, Fusion IV is unable to place any medications into interstate commerce although granted that right by Congress. The Board, the district court and the Ninth Circuit all argued cases relevant to the 'dormant commerce clause'.

XVI. FDCA EXPRESSLY PREEMPTS STATE LAW IN THE ENFORCEMENT OF OUTSOURCING FACILITIES WHICH WERE CREATED BY THE FDCA

This Court stated in *FDA v. Brown & Williamson Tobacco Corp.*, that in constitutional analysis, the FDCA must be considered as a whole. *FDA v. Brown & Williamson* (2000) 529 U.S. 120. The FDCA prohibits "enforcement" other than by the United States. 21 U.S.C. §271(a) and §337. FDCA has authority to enforce the operation of outsourcing facilities and expressly preempts state enforcement. Enforcement necessarily includes 'licensing', discipline and regulation by California. California law by its mere existence and language is in conflict with the published instructions and notices of discretionary enforcement decisions provided by the FDA. The FDA warned states to not legislate in conflict with federal law. *Petitioners' 9th Circuit Opening Briefs*.

21 U.S.C. 353b defines an outsourcing facility as a facility … that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B. Presently and since 2013, a majority of states have further legislated a varying degree of requirements, almost all requiring 'licenses' from other states, after the enactment

of 21 U.S.C. §353b in 2013 (the whole purpose of which was to remove conflicting oversight from the states).

XVII. THE NINTH CIRCUIT IGNORED SUPREME COURT PRECEDENT ENTIRELY AS TO CALIFORNIA'S LICENSING REQUIREMENTS AND INPUT LANGUAGE INTO THE STATUTE WHICH WAS NOT THERE

State law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz* (1941) 312 U.S. 52, 67. See generally *Capital Cities Cable, Inc. v. Crisp (1984) 467 U.S. 691, 698-699.* "We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes." See *Capital Cities Cable, Inc. v. Crisp*, supra, at 699; *Fidelity Federal Savings & Loan Assn. v. De la Cuesta,* 458 U.S. 141, 153-154 (1982); *United States v. Shimer,* 367 U.S. 374, 381-383 (1961).

The Ninth Circuit ignored Supreme Court precedent entirely and found 'no conflict' between the DQSA and California law. The Ninth Circuit stated that in its view, California's licensing requirement did not conflict because California 'only' required that an outsourcing facility 'register' with the federal government. *9th Cir. Opinion.* This is nonsensical and untrue and does not resolve the issue. *Bus & Prof. Code* §4129.1 states: (a) An outsourcing facility that is licensed with the [FDA] … and shall also be licensed by the board as an outsourcing facility before

doing business within this state. The license shall be renewed annually…; (b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities; (c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board. (d) An outsourcing facility license shall not be issued or renewed until the board does all of the following …". *Emphasis added.*

This Court will note that there is NO language or consideration of "complementary state regulation" language anywhere in 21 U.S.C. §353b. The word "state" appears only in one line in the federal statute and that is to authorize licensing fees if a state licensed pharmacy is also present in the facility. Unlike 21 U.S.C. §353b involving outsourcing facilities, the portion of this statute which amended 353a involving state licensed pharmacies DID have language regarding state involvement.

The FDCA must be considered as a whole in determining congressional intent. The language present in 21 U.S.C. §353a and §353a(a), as opposed to 21 U.S.C. §353b, is instructive. Congress is explicit in §353a in defining how state agencies will communicate with the Secretary. The lack of similar language or even a suggestion of state involvement in licensing/enforcement of 21 U.S.C. §353b is instructive as to congressional intent.

XVIII. HEALTH AND WELFARE OF CITIZENS OF THE UNITED STATES ARE AFFECTED BY LEGISLATION RELATING TO OUTSOURCING FACILITIES WHICH ARE THE ONLY VEHICLES TO PLACE COMPOUNDED DRUGS INTO INTERSTATE COMMERCE

The health and welfare of the citizens of the United States is affected to a great extent by the confusion created by disparate state regulation of federal outsourcing facilities. Such disparate state regulation was the reason Congress enacted the federal statute in 2013. Federal outsourcing facilities are the only means of placing compounded medications into interstate commerce in the event of a "shortage" of FDA approved pharmaceutical drugs, or for a clinical need for such compounds, and in the event of a national emergency. The Ninth Circuit's decision is a truly dangerous decision to let lie.

XIX. CONCLUSION

Petitioners respectfully ask this Court to grant this petition for writ of certiorari, due to the conflict of not only California's laws, but the laws of a majority of states which unfortunately and tragically conflict with the purpose of Congress' enactment of 21 U.S.C. §353b.

Dated March 1, 2021

Al Mohajerian
Counsel of Record
Ann Anooshian
Mohajerian, APLC
1901 Avenue of the Stars, Suite 1100
Los Angeles, CA 90067
(310) 556-3800
al@mohajerian.com
Counsel for Petitioners

APPENDIX

APPENDIX A — MEMORANDUM OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED JUNE 17, 2020

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 19-55791

FUSION IV PHARMACEUTICALS, INC., DBA AXIA PHARMACEUTICAL, A CALIFORNIA CORPORATION; NAVID VAHEDI, PHARM D.,

Plaintiffs-Appellants,

v.

ANNE SODERGREN, IN HER OFFICIAL CAPACITY AS THE INTERIM EXECUTIVE OFFICER OF THE CALIFORNIA STATE BOARD OF PHARMACY,

Defendant-Appellee,

and

CALIFORNIA STATE BOARD OF PHARMACY; *et al.*,

Defendants.

Appendix A

Appeal from the United States District Court
for the Central District of California.
D.C. No. 2:19-cv-01127-PA-FFM
Percy Anderson, District Judge, Presiding.

MEMORANDUM[*]

June 1, 2020,[**] Submitted, Pasadena, California
June 17, 2020, Filed

Before: RAWLINSON and N.R. SMITH, Circuit Judges, and KORMAN,[***] District Judge.

Fusion IV Pharmaceuticals, Inc. ("Fusion IV") appeals the district court's grant of judgment on the pleadings. Fusion IV argues that California's regulatory requirements: (1) are preempted by the Drug Quality and Security Act ("DQSA" or "Act"), *see* Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587-640 (2013); or, alternatively, (2) violate the Commerce Clause's protections against state laws that unreasonably burden Federal law. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.[1]

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* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).

*** The Honorable Edward R. Korman, United States District Judge for the Eastern District of New York, sitting by designation.

1. The motion of the National Association of Boards of Pharmacy, the Arkansas State Board of Pharmacy, the Kansas

Appendix A

1. The district court properly found there was no preemption. *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015).

A. There is no express preemption, because the DQSA does not "explicitly manifest[] Congress's intent to displace state law" dealing with mass compounding. *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1022 (9th Cir. 2013) (quoting *United States v. Alabama*, 691 F.3d 1269, 1281 (11th Cir. 2012)). Thus, there can be no express preemption by negative implication, because express preemption, by its very definition, cannot be implied. *See Gadda v. Ashcroft*, 377 F.3d 934, 944 (9th Cir. 2004).

B. There is also no field preemption, because "the scheme of federal regulation" at issue here is not "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98, 112 S. Ct. 2374, 120 L. Ed. 2d 73 (1992) (internal quotation marks omitted) (quoting *Fidelity Fed. Sav. & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982)). Because the DQSA clearly allows for "complementary state regulation[s]," Fusion IV's field preemption claims fail. *See Arizona v. United States*, 567 U.S. 387, 401, 132 S. Ct. 2492, 183 L. Ed. 2d 351 (2012).

State Board of Pharmacy, the Louisiana Board of Pharmacy, the Michigan Board of Pharmacy, the Mississippi Board of Pharmacy, the North Dakota State Board of Pharmacy, the State of Ohio Board of Pharmacy, and the Oklahoma State Board of Pharmacy for leave to file a brief in support of Defendant—Appellee as *amicus curiae*, *see* Dkt. 24, is also granted.

C. There is no conflict preemption, because it is not "impossible for a private party to comply with both state and federal [compounding] requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990). Importantly, it is possible to obtain authorization under both the state and federal regulatory schemes, because California does not necessarily require anything more than registration with the FDA before a facility can acquire a state license. *See* Cal. Bus. & Prof. Code § 4129.1(d)(2).

2. The district court properly found that the applicable California licensing requirements do not violate dormant Commerce Clause principles. Fusion IV failed to establish that the requirements impose a "substantial burden" on interstate commerce. *See Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012).

AFFIRMED.

APPENDIX B — UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, FILED JUNE 21, 2019

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

CV 19-1127 PA (FFMx)

FUSION IV PHARMACEUTICALS, INC., *et al.*,

v.

EXECUTIVE DIRECTOR VIRGINIA HEROLD, *et al.*,

PERCY ANDERSON, UNITED STATES DISTRICT JUDGE

June 21, 2019, Decided
June 21, 2019, Filed

CIVIL MINUTES - GENERAL

Proceedings: IN CHAMBERS - COURT ORDER

Before the Court are a Motion for Judgment on the Pleadings Pursuant to FRCP 12(c) (Docket Nos. 47, 49)[1] filed by plaintiffs Fusion IV Pharmaceuticals, Inc. d/b/a Axia Pharmaceutical ("Fusion IV") and Navid Vahedi ("Vahedi") (collectively, "Plaintiffs") and a Motion for

1. Plaintiffs have filed two identical versions of their motion.

Judgment on the Pleadings (Docket No. 52) filed by defendant Anne Sodergren, Interim Executive Officer of the California State Board of Pharmacy ("Defendant"). Pursuant to Rule 78 of the Federal Rules of Civil Procedure and Local Rule 7-15, the Court finds these matters appropriate for decision without oral argument. The hearing calendared for June 24, 2019 is vacated, and the matters taken off calendar.

I. Background

"Generally, the [Food, Drug, and Cosmetic Act ('FDCA')] and parallel state statutes require approval by the FDA and other state agencies before drugs can be sold. Compounded drugs are exempted from these requirements, inter alia, under both federal and state laws when certain conditions are met." *Allergan USA, Inc. v. Prescribers Choice, Inc.*, 364 F. Supp. 3d 1089, 1103-04 (C.D. Cal. 2019) (citations omitted). With this action, Plaintiffs challenge the validity of certain state laws concerning compounded drugs.

"In 2013, Congress passed the Drug Quality and Security Act ('DQSA'), amending FDCA Section 503A and adding Section 503B." *Allergan USA, Inc. v. Prescribers Choice, Inc.*, 364 F. Supp. 3d 1089, 1103-04 (C.D. Cal. 2019) (citing DQSA, 113 Pub. L. No. 54, 127 Stat. 587 (2013)). Section 503B of the FDCA allows a drug-compounding facility to avoid certain regulatory requirements for a drug, such as the new drug approval process, if the drug is compounded in a facility that has registered as an "outsourcing facility" with the Food

and Drug Administration ("FDA") and other conditions are satisfied. *Id.* § 353b(a), (b). California law requires that an outsourcing facility registered with the FDA "be concurrently licensed with the [California Board of Pharmacy (the 'Board')] . . . if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California." Cal. Bus. & Prof. Code § 4129; *see id.* §§ 4129.1, .2. The state license must be renewed annually, and the facility must undergo an inspection by and provide certain information to the Board in order to obtain or renew a license. *Id.* §§ 4129.1, .2.

According to the operative Third Amended Complaint ("TAC"), Fusion IV is a federally registered outsourcing facility. (Docket No. 40 at 1, 11-12, 25.) After Fusion IV received its federal registration, Plaintiffs applied for a California outsourcing facility license, but the Board (improperly, in Plaintiffs' view) denied their application. (*Id.* at 1, 3, 26.) Plaintiffs contend that Congress intended for outsourcing facilities to be subject only to federal regulation; the California laws governing outsourcing facilities conflict with federal law in various ways; and the California laws impermissibly interfere with interstate commerce. (*See generally* TAC.) Plaintiffs thus argue that the state laws are preempted and also invalid under the United States Constitution's Commerce Clause. (*Id.* at 2.) Plaintiffs seek declaratory relief including, among other things, an order ruling the state outsourcing facility laws invalid and holding that Plaintiffs are subject only to federal regulation in their outsourcing-facility activities. (*Id.* at 38-39.)

Appendix B

Plaintiffs and Defendant have filed motions for judgment on the pleadings. As in their TAC, Plaintiffs argue that California's outsourcing facility laws are preempted by federal law under theories of express, field, and implied preemption and also invalid under the Commerce Clause. (*See* Pls.' Mot.; Pls.' Opp'n to Def.'s Mot., Docket No. 58.[2]) Defendant argues that the state laws are valid. (*See* Def.'s Mot.; Def.'s Opp'n to Pls.' Mot., Docket No. 55.)

II. Legal Standard

Under Federal Rule of Civil Procedure ("Rule") 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." In ruling on a motion for judgment on the pleadings brought pursuant to Rule 12(c), "the allegations of the non-moving party must be accepted as true, while the allegations of the moving party which have been

2. Plaintiffs' opposition to Defendant's motion exceeds the applicable page limit and was untimely. *See* L.R. 7-9; L.R. 11-6. (*See also* Docket No. 22 at 5.) Defendant argues that the opposition should be disregarded, Defendant's motion should be granted or the case dismissed, and Plaintiffs should be sanctioned for these and other violations of the Local Rules. (Def.'s Reply at 1-3, Docket No. 59.) Plaintiffs have filed motions to exceed the page limitation and to have their opposition considered despite its untimeliness. (Docket Nos. 60, 62, 63.) Plaintiffs' arguments in their opposition are essentially the same as those in their own motion, and the Court ultimately concludes that Defendant is entitled to Judgment in its favor even if Plaintiffs' opposition is considered. Accordingly, the Court considers Plaintiff's opposition despite these procedural deficiencies.

denied are assumed to be false." *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1550 (9th Cir. 1990) (citing *Doleman v. Meiji Mutual Life Ins. Co.*, 727 F.2d 1480, 1482 (9th Cir. 1984); *Austad v. United States*, 386 F.2d 147, 149 (9th Cir. 1967)). Rule 12(c) is "functionally identical" to Rule 12(b)(6), and the same standard "applies to motions brought under either rule." *Cafasso v. Gen. Dynamics C4 Sys.*, 637 F.3d 1047, 1054 n.4 (9th Cir. 2011). Therefore, whether a motion is brought under Rule 12(b)(6) or Rule 12(c), the pleadings must satisfy the "plausibility standard," in which the complaint must "raise a reasonable expectation that discovery will reveal evidence of [the alleged infraction]." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). For a complaint to meet this standard, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555 (citing 5 C. Wright & A. Miller, *Federal Practice and Procedure* §1216, pp. 235-36 (3d ed. 2004) ("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action")); *see also Daniel v. Cty. of Santa Barbara*, 288 F.3d 375, 380 (9th Cir. 2002) ("All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." (quoting *Burgert v. Lokelani Bernice Pauahi Bishop Tr.*, 200 F.3d 661, 663 (9th Cir. 2000))). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotation marks omitted). In construing the *Twombly* standard, the Supreme Court

has advised that "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009).

"Judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law." *Hal Roach Studios*, 896 F.2d at 1550 (citing *Doleman*, 727 F.2d at 1482). Alternatively, the Court has discretion to grant leave to amend or to dismiss causes of action rather than grant judgment on a Rule 12(c) motion. *See Lonberg v. City of Riverside*, 300 F. Supp. 2d 942, 945 (C.D. Cal. 2004); *Carmen v. S.F. Unified Sch. Dist.*, 982 F. Supp. 1396, 1401 (N.D. Cal. 1997).

III. The Parties' Requests for Judicial Notice

"In a motion for judgment on the pleadings, the Court may consider information 'contained in materials of which the court may take judicial notice' and documents attached to the complaint." *Mays v. Wal-Mart Stores, Inc.*, 354 F. Supp. 3d 1136, 1141 (C.D. Cal. 2019) (quoting *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999); and citing *United States v. Ritchie*, 342 F.3d

903, 908 (9th Cir. 2003))). Both sides have filed requests for judicial notice (Docket Nos. 44, 53, 56), and neither side has opposed to the others' requests.

Among other things, Plaintiffs request that the Court take judicial notice of the "fact" that Section 503B of the FDCA "establishes a registration 'authorization' in order for outsourcing facilities to begin to conduct business in compounding drugs to be placed into interstate commerce." (Docket No. 44 at 1.) The Court denies this request because the purported fact is a legal conclusion about the effect of a statute at issue in this case. *See, e.g.*, *United States v. Molen*, No. 2:10-cv-02591 MCE KJN PS, 2011 U.S. Dist. LEXIS 53995, 2011 WL 1810449, at *6 (E.D. Cal. May 9, 2011) ("[T]here is typically no need to request judicial notice of statutes and regulations pursuant to Federal Rule of Evidence 201 . . . . Instead of requesting 'judicial notice' of statutes and regulations they believe support their arguments, [parties] should simply include citations to the statutes and regulations within the legal argument portion of their motions.").

Plaintiffs also request that the Court take judicial notice of the fact that in 2012, there was an "incident involving adulterated compounded drugs which occurred in Massachusetts, leading to the deaths of sixty-four individuals and the illness of over 700 others, who contracted fungal meningitis, as reflected in [material on a webpage maintained by the United States Senate] (and Congressional Record excerpts within Plaintiffs' Complaint)." (Docket No. 44 at 2.) The Court grants this request. *See, e.g., Anderson v. Holder*, 673 F.3d 1089, 1094

n.1 (9th Cir. 2012); *Hadley v. Kellogg Sales Co.*, 243 F. Supp. 3d 1074, 1087 (N.D. Cal. 2017).

The remainder of the materials provided by the parties are not relevant to the disposition of their motions. The Court denies the parties' requests as moot with respect to those materials. *See, e.g., Bryant v. Mickelsen*, 551 F. App'x 348, 349 (9th Cir. 2014).

IV. Discussion

A. Preemption

As a preliminary matter, a "presumption against preemption applies generally, but is especially strong when . . . 'Congress has legislated in a field which the states have traditionally occupied.'" *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1141 (9th Cir. 2015) (quoting *McDaniel v. Wells Fargo Invs., LLC*, 717 F.3d 668, 674 (9th Cir. 2013); and citing *Bayside Fish Flour Co. v. Gentry*, 297 U.S. 422, 426, 56 S. Ct. 513, 80 L. Ed. 772 (1936)). Plaintiffs suggest at various points in the TAC and their briefing that "there is no 'traditional state regulation' which would create a presumption that a federal statute does not supplant state law." (TAC at 6-7, 37; *see* Pls.' Mot. at 12; Pls.' Opp'n to Def.'s Mot. at 11-12.) However, as Defendant argues, drug compounding predates the federal outsourcing facility laws and was regulated by the states. (Def.'s Opp'n to Pls.' Mot. at 2-3; Def.'s Reply at 3.) *See* Stacey L. Worthy et al., *The Compounding Conundrum: How Insufficient Delineation of Regulatory Responsibility Has Created a Need for State and Federal*

Drug Law Reform, 72 Food & Drug L.J. 506, 508 (2017) ("While the regulation of new drugs falls under FDA's federal authority, the practice of pharmacy and medicine has traditionally been under the states' purview. Therefore, given that compounded drugs are produced by pharmacies or physicians, they have long fallen under state oversight." (footnotes omitted)); Nathan A. Brown & Eli Tomar, *Could State Regulations Be the Next Frontier for Preemption Jurisprudence?: Drug Compounding as a Case Study*, 71 Food & Drug L.J. 271, 272, 288, 295 (2016) (noting that "states have long been actively engaged in compounding oversight"). Additionally, regulation of drug compounding is more broadly an issue of public health or safety, and the Supreme Court has specifically noted a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985). Accordingly, the "California [outsourcing facility] statute[s] cannot be set aside absent 'clear evidence' of a conflict" with federal law. *See Chinatown Neighborhood Ass'n*, 794 F.3d at 1141-42 (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000); and citing *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015)).

Plaintiffs also contend that California law explicitly acknowledges federal preemption by providing that an outsourcing facility's state license is immediately canceled, revoked, or suspended upon the FDA's cancellation, revocation, or suspension of its federal registration. (TAC at 21-22; Pls.' Mot. at 35-36; Pls.' Opp'n to Def.'s Mot. at 33-

34.) Under California law, "[i]f the [FDA] cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to Section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law." Cal. Bus. & Prof. Code § 4303.1. As Defendant points out, "this section simply states that FDA registration is a prerequisite to holding a state outsourcing facility license." (Def.'s Opp'n to Pls.' Mot. at 15 n.2; *see* Def.'s Reply at 7.) *See also* Cal. Bus. & Prof. Code § 4129.2(a). Contrary to Plaintiffs' suggestion, the California legislature's decision to automatically revoke a state license upon loss of a federal registration does not mean that the state must grant a license if a federal registration is issued.

1. Express Preemption

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' Under this principle, Congress has the power to preempt state law. There is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision." *Arizona v. United States*, 567 U.S. 387, 398, 132 S. Ct. 2492, 183 L. Ed. 2d 351 (2012) (citations omitted).

Plaintiffs assert that Congress expressly preempted state regulation of outsourcing facilities in Section 503B(a)(11) and (d)(4)(A) of the FDCA as well as the DQSA's prohibition of state product-tracing requirements. (TAC

at 9, 17, 27; *see* Pls.' Mot. at 32, 36, 39; Pls.' Opp'n to Def.'s Mot. at 10-11, 20.) However, none of these, nor any other provisions in the FDCA, expressly preempt state regulation of outsourcing facilities.

Section 503B(a)(11) of the FDCA provides that a drug is exempt from certain regulatory requirements if, among other conditions, the "drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section." 21 U.S.C. § 353b(a)(11). This provision simply states that the exemption only applies if the drug is compounded in accordance with Section 503B's requirements; it does not state that other regulation is not possible.

Section 503B(d)(4)(A) defines "outsourcing facility" to mean "a facility at one geographic location or address that--(i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section." 21 U.S.C. § 353b(d)(4)(A). This provision merely establishes what the term "outsourcing facility" means in the context of the statute, and it reiterates that the federal regulatory exemption only applies if an entity complies with certain specific requirements.

Finally, the portion of the DQSA concerning product-tracing that Plaintiffs cite provides that "[b]eginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system" that are inconsistent with, stricter than, or in addition to

certain specified federal laws and regulations. 21 U.S.C. § 360eee-4(a). However, the statute makes clear that "[n]othing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) . . . ." *Id.* § 360eee-4(c). The state laws that Plaintiffs are challenging are not "related to product tracing" and therefore are explicitly excluded from the provision's preemptive scope. Furthermore, this provision is located in the Drug Supply Chain Security Act, a separate title in the DQSA from the Compounding Quality Act, which created Section 503B of the FDCA. *See* DQSA. The existence of a provision explicitly preempting some state regulation "impl[ies] that Congress intentionally did not preempt state law generally, or in respects other than those it addressed." *Keams v. Tempe Tech. Inst., Inc.*, 39 F.3d 222, 225 (9th Cir. 1994).

Plaintiffs also contend that the DQSA's legislative history demonstrates Congress's intent to preempt state regulation, including legislators' remarks prior to passage of the bill. (*See* TAC Ex. H, Docket No. 40-2 at 1-11.) For example, shortly before the bill's passage, one senator stated that under the new law, "[s]terile compounding facilities that do not want to comply with the patchwork of State laws and requirements can choose instead to have FDA regulate their compounding." (TAC Ex. H, Docket No. 40-2 at 3; *see also id.* at 10-11.) Another senator stated that the DQSA "aims to address [the] regulatory gray area [of mass compounding] by clarifying the responsibilities of the FDA with regard to the oversight of mass compounded

pharmaceuticals. . . . Under this bill, mass compounding pharmacies can choose to register as outsourcing facilities that would be subject to new FDA regulatory oversight similar to that of other pharmaceutical manufacturers." (*Id.* at 5; *see also id.* at 10-11; TAC Ex. G., Docket No. 40-1 at 43-92 (Government Accountability Office report discussing lack of clarity concerning regulatory authority and this legislative history).) But the view of one or two legislators is not sufficient to establish Congress's intent. *See Chinatown Neighborhood Ass'n*, 794 F.3d at 1144 n.7 (stating that "a lone statement in the legislative history is not a 'clear and manifest' expression of Congress's intent to preempt"). Moreover, the legislative materials provided by Plaintiffs show that Congress's primary motivation in enacting the DQSA was public safety in light of a recent meningitis outbreak, not merely to establish a uniform system of regulation or to increase the availability of certain drug products as Plaintiffs contend. The senators' remarks in particular suggest that Congress was acting to fill a regulatory gap that had existed with respect to mass compounders, and to clarify that the FDA would be responsible for that regulation under the new law. On the whole, it does not clearly establish that Congress intended the FDA alone to have regulatory authority going forward.

Plaintiffs also allege that Congress's intent to preempt state law is confirmed by the FDA, which "has spoken and advised states against legislation which conflicts with 21 U.S.C. § 353b." (TAC at 8, 18-21; *see* Pls.' Mot. at 25, 32-35; Pls.' Opp'n to Def.'s Mot. at 10, 20-25.) The Supreme Court "has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements." *Wyeth*

v. Levine, 555 U.S. 555, 576, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009) (citing *Geier*, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914; *Hillsborough County*, 471 U.S. at 713). But Plaintiffs have not identified any agency regulations and instead provide only unpublished documents apparently created for a meeting between FDA and state officials. (TAC Ex. A, Docket No. 40-1 at 1-21; TAC Ex. B, Docket No. 40-1 at 22-27.) *See Wyeth*, 555 U.S. at 576-78 (stating that the "weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness," and declining to afford deference to a statement concerning preemption in the preamble to an FDA regulation). Moreover, the materials provided do not show that the FDA believed Congress to have preempted state law or that FDA regulations would preempt state law. To the contrary, the materials reflect the FDA's understanding that state licensure and regulation of outsourcing facilities was possible, and even recommended, although the FDA expressed general concerns about varying state regulatory approaches and the possibility of different state and federal standards. (*See, e.g.*, TAC Ex. A, Docket No. 40-1 at 16 (stating that the FDA "recommend[s] that states create a licensure or registration category specific to outsourcing facilities" and that "[c]ompliance with federal law applicable to outsourcing facilities should be a condition of state licensure or registration under this category").

Accordingly, Plaintiffs fail to establish that Congress expressly preempted state regulation of outsourcing facilities.

2. Field Preemption

"Under the doctrine of 'field preemption,' state law is preempted if it regulates 'conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.'" *Chinatown Neighborhood Ass'n*, 794 F.3d at 1141 n.5 (citation omitted) (quoting *Arizona*, 567 U.S. at 399). "The intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Arizona*, 567 U.S. at 399 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S. Ct. 1146, 91 L. Ed. 1447 (1947); and citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990)).

Plaintiffs allege that Congress enacted the DQSA "in order to *oversee and regulate the national distribution of compounded drugs*" and to create the category of "outsourcing facilities," which "would be regulated by the FDA under very strict guidelines and oversight." (TAC at 5-7, 10, 16-17; *see* Pls.' Mot. at 36-40.) Plaintiffs also allege that "the federal scheme in enacting 21 U.S.C. § 353b is so pervasive as to leave no room for states to supplement with further regulations" and that "the dominance of the federal interest in compounding of sterile drugs to be distributed in interstate commerce, is shown by the enactment of the Drug Quality and Security Act after a fatal incident of tainted compounded drugs." (TAC at 10, 16-17, 31; *see* Pls.' Mot. at 13-15, 25-26.) However, "[t]he

mere existence of a detailed regulatory scheme does not by itself imply preemption of state remedies." *Keams*, 39 F.3d at 225-26 (citing *English*, 496 U.S. at 87). Nor does the Court find that an intent to preempt the field must be inferred due to a strong federal interest in the field. *See Hillsborough County*, 471 U.S. at 719 ("Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law. . . . [A]s we have stated, the regulation of health and safety matters is primarily, and historically, a matter of local concern." (citing *Rice*, 331 U.S. at 230)). Indeed, that the DQSA included a limited express preemption provision elsewhere but not in the Compounding Quality Act suggests that Congress did not intend to preempt state regulation of outsourcing facilities. *See Keams*, 39 F.3d at 225-26.

Moreover, the statute actually contemplates some concurrent state regulation. For example, Section 503B of the FDCA provides that payment of the federal registration fee "shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees." 21 U.S.C. § 353b(d). Additionally, it requires an outsourcing facility to be supervised by a licensed pharmacist in order for the regulatory exemptions to apply, *id.* § 353b(a), and pharmacist licensure is handled by state boards of pharmacy. *See* Cal. Bus. & Prof. Code §§ 4036, 4200(a); *see also Ouellette v. Mills*, 91 F. Supp. 3d 1, 9 (D. Me. 2015) ("Pharmacist licensure does indeed implicate the traditionally local sphere of public health

and safety. The [FDCA] does not regulate the licensure of pharmacists; it instead leaves that area to individual states." (citing 21 U.S.C. §§ 360(g), 384(a)(2))). The DQSA also directed "the Comptroller General of the United States [to] submit to Congress a report on pharmacy compounding and the adequacy of State and Federal efforts to assure the safety of compounded drugs." DQSA § 107(a). The report was required to include, among other things, "a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies" and "an evaluation of the effectiveness of the communication among States and between States and the Food and Drug Administration regarding compounding." DQSA § 107(b)(2), (4). It thus does not appear that Congress intended the DQSA to supplant the states' role in regulating compounded drugs generally or outsourcing facilities specifically.

Plaintiffs again point to the DQSA's legislative history and the FDA's statements as supporting a finding of field preemption. (TAC at 28-32; *see* Pls.' Mot. at 26-27, 36-40; Pls.' Opp'n to Def.'s Mot. at 19, 24.) However, for the reasons already discussed, the legislative history does not establish Congress's intent to preempt state regulation, and Plaintiffs' submissions show that the FDA actually supports state licensure and regulation of outsourcing facilities.

The Court thus concludes that Congress did not intend to preempt the field of regulation with respect to compounding facilities.

3. Conflict Preemption

"[A] federal statute has preemptive effect if it conflicts with state law. This can occur when 'compliance with both federal and state regulations is a physical impossibility,' or when a state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Chinatown Neighborhood Ass'n*, 794 F.3d at 1141 (citation omitted) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963); and then *Arizona*, 567 U.S. at 399-400).

Plaintiffs allege that California's outsourcing facility laws and regulations conflict with federal law in a number of ways, including by preventing Plaintiffs from compounding bulk drug substances, and in particular ziconotide; by not allowing certain FDA-approved methods of sterility testing; by defining terms differently from federal law; by requiring different "engineering controls"; by imposing different invoicing requirements; and by having differing training requirements for the Board's inspectors. (TAC at 2, 11-14, 16; Pls.' Mot. at 21-23, 28-32; Pls.' Opp'n to Def.'s Mot. at 27-32.) However, Plaintiffs fail to identify a state law or regulation actually conflicting with federal law as to any of these subjects. California's outsourcing facility statutes provide that outsourcing facilities "shall compound all sterile products and nonsterile products in compliance with regulations issued by the [Board] and with federal current good manufacturing practices applicable to outsourcing facilities." Cal. Bus. & Prof. Code § 4129.1(b); *see id.* § 4129.2(b). California law thus subjects

outsourcing facilities to both federal and state standards, but it otherwise does not address any of the alleged areas of conflict that Plaintiffs cite, and the Board has not yet implemented any regulations concerning compounding at outsourcing facilities. *See* Cal. Bus. & Prof. Code §§ 4129 to 4129.9; Cal. Code Regs. tit. 16, arts. 4.5, 7. (*See also* Def.'s Opp'n to Pls.' Mot. at 9 n.2, 13.)

Plaintiffs also argue that state and federal laws conflict because federal law requires Fusion IV to have a licensed pharmacist overseeing its compounding activities, but "California will not license Fusion IV as an outsourcing facility" and "continues to discipline Fusion IV as a 'pharmacy.'" (TAC at 3, 11, 14; Pls.' Mot. at 21, 28-29; Pls.' Opp'n to Def.'s Mot. at 17-18.) For the regulatory exemptions under Section 503B of the FDCA to apply, a drug must be "compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility." 21 U.S.C. § 353b(a). California law prohibits an outsourcing facility from also being licensed as a sterile compounding pharmacy and from performing the duties of a pharmacy. Cal. Bus. & Prof. Code § 4129(b), (e). However, California law does not prohibit an individual who is a licensed pharmacist from supervising the compounding of a drug at an outsourcing facility. That Plaintiffs are not able to obtain a state outsourcing facility license is not evidence of a conflict between state and federal laws but rather is the result of circumstances particular to them. And although Plaintiffs contend that the state's denial of their license was improper, those issues are not before the Court in this action. (*See, e.g.*, TAC at 1-2 (stating that the denial of

Plaintiffs' application "*is not at issue herein — Plaintiffs appealed and a hearing was held, and ensuing writ of administrative mandamus filed — relating to the state proceedings. This complaint is entirely based upon the federal preemption issues/interstate commerce issues.*"); *see also* Docket Nos. 41, 42.)

Plaintiffs also argue that "federal law ***allows an outsourcing facility to also have a state licensed pharmacy*** on its premises. California law prohibits this. While this does not make it impossible for an outsourcing facility to 'function', it makes it impossible for an outsourcing facility to *choose to have a pharmacy on its premises* as expressly provided for under federal law." (TAC at 16; *see id.* at 19; Pls.' Opp'n to Def.'s Mot. at 31.) Under Section 503B, "[a]n outsourcing facility is not required to be a licensed pharmacy," and it "may or may not obtain prescriptions for identified individual patients." 21 U.S.C. § 353b(d)(4)(B), (C). California law provides that "[a] facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location" and an "outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients." Cal. Bus. & Prof. Code § 4129(b), (e). However, "the possibility of proscription by [a state] of conduct that federal law might permit is not sufficient to warrant preemption." *Chevron U.S.A., Inc. v. Hammond*, 726 F.2d 483, 498 (9th Cir. 1984) (quoting *William Inglis & Sons Baking Co. v. ITT Continental Baking Co.*, 668 F.2d 1014, 1049 (9th Cir.1981); and citing *Fla. Lime & Avocado*

Growers, 373 U.S. 132, 83 S. Ct. 1210, 10 L. Ed. 2d 248). As Plaintiffs acknowledge, it is not impossible to comply with both the state and federal laws. *Cf. N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 582-83 (9th Cir. 1983) ("While the state standards are more stringent than the federal standards, it is possible to comply with both. We hold that there is no actual conflict between [the state law] and the federal . . . laws." (citing *Fla. Lime & Avocado Growers*, 373 U.S. at 141-43)).

Plaintiffs also cite the possibility of varying requirements among states as supporting a finding of preemption. (TAC at 15.) But without further evidence of Congress's intent to preempt state law, whether and to what extent California's laws differ from other states' is not relevant. *See Keams*, 39 F.3d at 226 ("Congress could have avoided diversity by express preemption, had it wished to do so, yet it did not."). The Court also finds that Congress's primary motivation in enacting the DQSA appears to have been public safety and to ensure that mass compounding was subject to some regulation, not necessarily to establish a uniform, nationwide standard of regulation. *See, e.g., Chamberlain v. Ford Motor Co.*, 314 F. Supp. 2d 953, 962-63 (N.D. Cal. 2004) (finding no preemption where primary congressional objective was safety rather than uniform administration).

Ultimately, most of Plaintiffs' arguments boil down to a dispute over whether they must obtain a state license at all. Plaintiffs contend that California's statutes and licensure requirement for outsourcing facilities are preempted because they interfere with the use of

Plaintiffs' federal license. (TAC at 3, 4, 8-9, 11-14, 19, 21-22, 24, 26-28, 32-33; Pls.' Mot. at 15-21; Pls.' Opp'n to Def.'s Mot. at 9-10, 11-18.) It is true that a "State may not enforce licensing requirements which, though valid in the absence of federal regulation, give the State's licensing board a virtual power of review over the federal determination that a person or agency is qualified and entitled to perform certain functions, or which impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress. No State law can hinder or obstruct the free use of a license granted under an act of Congress." *Sperry v. State of Florida*, 373 U.S. 379, 385, 83 S. Ct. 1322, 10 L. Ed. 2d 428, 1963 Dec. Comm'r Pat. 211 (1963) (footnotes and internal quotation marks omitted). But the mere fact of concurrent licensure does not establish preemption. *See, e.g., UFO Chuting of Haw., Inc. v. Smith*, 508 F.3d 1189, 1192-93 (9th Cir. 2007) ("No State may completely exclude federally licensed commerce. However, a state may impose upon federal licensees reasonable, nondiscriminatory conservation and environmental protection measures otherwise within their police power." (alteration, citations, and internal quotation marks omitted)); *see also* Brown & Tomar, *supra*, at 295 ("It is unlikely that Congress specifically intended to prohibit states from licensing outsourcing facilities.").

Moreover, as Defendant argues, the wording of the DQSA suggests that "registration as an outsourcing facility with the FDA is voluntary." (Def.'s Opp'n to Pls.' Mot. at 2-3 (emphasis omitted) (citing 21 U.S.C. § 353b(a)).) *See also* 21 U.S.C. § 353b(d)(4)(A)(ii) (defining "outsourcing facility" as a facility that, among other things, "has *elected*

to register as an outsourcing facility" (emphasis added)). Registration itself does not bestow any benefits but is one prerequisite for a facility's avoidance of certain regulatory requirements for a particular drug. *See id.* § 353b(a), (b); Worthy et al., *supra*, at 524 ("Under the FDCA, registering with FDA is voluntary. Only those compounders that wish to be classified as outsourcing facilities under section 503B [of the FDCA] must do so."); Brown & Tomar, *supra*, at 296 ("[I]t is not clear that registration with FDA under section 503B constitutes a 'license' to engage in outsourcing beyond the scope of practice permitted under state law. The statutory language could be read to suggest only that compliance with section 503B provides a license, or exemption, from more onerous requirements of *federal* law, such as premarket approval for new drugs."); *see also Wisc. Pub. Intervenor v. Mortier*, 501 U.S. 597, 613-14, 111 S. Ct. 2476, 115 L. Ed. 2d 532 (1991) ("FIFRA nowhere seeks to establish an affirmative permit scheme for the actual use of pesticides. It certainly does not equate registration and labeling requirements with a general approval to apply pesticides throughout the Nation without regard to regional and local factors like climate, population, geography, and water supply. Whatever else FIFRA may supplant, it does not occupy the field of pesticide regulation in general or the area of local use permitting in particular."). A lack of a registration does not prevent a facility from compounding drugs; it simply subjects them to other regulations. (TAC Ex. B, Docket No. 40-1 at 23 ("Compounders in the United States that have not registered with FDA as outsourcing facilities may produce drugs that are eligible for the exemptions under section 503A of the [FDCA].").)

Plaintiffs thus fail to establish that California's outsourcing facility laws conflict with federal law or present an obstacle to federal objectives.

B. The Commerce Clause

"The Commerce Clause grants Congress the power '[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes.' Despite its textual focus solely on congressional power, the Clause also has long been understood to have a negative aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce. This so-called 'dormant' Commerce Clause is driven by concern about economic protectionism — that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Am. Fuel & Petrochemical Mfrs. v. O'Keeffe*, 903 F.3d 903, 910 (9th Cir. 2018) (citations and some internal quotation marks omitted).

> "The Supreme Court has adopted a two-tiered approach to analyzing state economic regulation under the Commerce Clause. If a state statute directly regulates or discriminates against interstate commerce, or its effect is to favor in-state economic interests over out-of-state interests, it is struck down without further inquiry. When, however, a state statute has only indirect effects on interstate commerce and regulates evenhandedly, it violates the Commerce Clause only if the burdens of the

> statute so outweigh the putative benefits as to make the statute unreasonable or irrational." *Chinatown Neighborhood Ass'n*, 794 F.3d at 1145 (alterations, citations, and internal quotation marks omitted); *see O'Keeffe*, 903 F.3d at 910.

"[A] statute that treats all private companies exactly the same does not discriminate against interstate commerce." *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 947 (9th Cir. 2013) (alteration and internal quotation marks omitted) (quoting *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342, 127 S. Ct. 1786, 167 L. Ed. 2d 655 (2007)). California's outsourcing facility laws subject both instate and out-of-state outsourcing facilities to state licensure and to other requirements that are virtually the same, an a facility must only obtain a license "if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California." Cal. Bus. & Prof. Code § 4129(a); *see id.* §§ 4129.1, .2. The laws are facially neutral and do not impermissibly seek to regulate interstate or out-of-state commerce. *See, e.g., Pharm. Research & Mfrs. of Am. v. County of Alameida*, 768 F.3d 1037, 1042 (9th Cir. 2014) ("The Ordinance, both on its face and in effect, applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer. . . . In other words, the Ordinance does not discriminate . . . ."); *O'Keeffe*, 903 F.3d at 916-17 (rejecting argument that state regulation impermissibly regulated conduct wholly outside of the

state's borders because the regulation "expressly applies only to fuels sold in, imported to, or exported from Oregon").

Plaintiffs primarily contend that having to obtain a state license is an impediment to interstate commerce. (TAC at 33-34; *see* Pls.' Mot. at 40-42; Pls.' Opp'n to Def.'s Mot. at 25.) But the state's license requirement, without more, does not violate the dormant Commerce Clause. *See, e.g., Huron Portland Cement Co. v. City of Detroit*, 362 U.S. 440, 447, 80 S. Ct. 813, 4 L. Ed. 2d 852 (1960) ("The mere possession of a federal license . . . does not immunize a ship from the operation of the normal incidents of local police power, not constituting a direct regulation of commerce."); *Sixth Angel Shepherd Rescue Inc. v. Pa. SPCA*, No. CIV.A. 10-3101, 2011 U.S. Dist. LEXIS 15438, 2011 WL 605697, at *6 (E.D. Pa. Feb. 15, 2011) ("[R]equiring requiring a license to do business in a state is generally not an undue burden on interstate commerce." (citing *Quik Payday, Inc. v. Stork*, 549 F.3d 1302, 1312-13 (10th Cir. 2008))). Nor does Plaintiffs' personal inability to obtain a state license establish an undue burden on interstate commerce. *See Quik Payday*, 549 F.3d at 1312 ("[W]e turn to Quik Payday's argument based on the specifics of the KUCCC. It contends that subjecting it to regulation by multiple states will in fact create inconsistency that would unduly burden interstate commerce. . . . Quik Payday is not being penalized by Kansas for the way it renews loans, or even for the interest rate it charges. Its misconduct was a simple failure to get a Kansas license."); *see also O'Keeffe*, 903 F.3d at 914 ("The Commerce Clause 'protects the interstate market,

not particular interstate firms.'" (quoting *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127, 98 S. Ct. 2207, 57 L. Ed. 2d 91 (1978))).

Plaintiffs also refer to varying regulations among states. (TAC at 15, 34-36; Pls.' Mot. at 41-43; Pls.' Opp'n to Def.'s Mot. at 25-27, 33.) But such concerns are only relevant when one state attempts to regulate conduct in other states. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336-37, 109 S. Ct. 2491, 105 L. Ed. 2d 275 (1989); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th Cir. 2013). California's outsourcing facility laws permissibly regulate only those facilities producing medications for distribution into or within California. *See O'Keeffe*, 903 F.3d at 917; *see also Chinatown Neighborhood Ass'n*, 794 F.3d at 1145-46.

Furthermore, Defendants contend, and Plaintiffs concede, that California's outsourcing facility laws are motivated by a desire to protect public safety. (*See* Def.'s Mot. at 16, 20; Def.'s Opp'n to Pls.' Mot. at 16-17; Pls.' Mot. at 3, 14; Pls.' Opp'n to Def.'s Mot. at 7.) Because this is a "legitimate matter[] of local concern" and it implicates an area in which state and federal cooperation is contemplated, "[t]here is . . . no significant interference with interstate commerce." *See Chinatown Neighborhood Ass'n*, 794 F.3d at 1147; *see also Pharm. Research & Mfrs.*, 768 F.3d at 1042 (noting that "regulations that touch upon safety . . . are those that the [Supreme] Court has been most reluctant to invalidate. Indeed, if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with

related burdens on interstate commerce" (quoting *Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 670, 101 S. Ct. 1309, 67 L. Ed. 2d 580 (1981))).

Accordingly, Plaintiffs fail to establish that California's outsourcing facility laws are invalid under the Commerce Clause.

CONCLUSION

Plaintiffs fail to demonstrate that California's outsourcing facility laws are preempted by federal law or that they are invalid under the Commerce Clause. For the foregoing reasons, Plaintiffs' motions to exceed the page limitation for their opposition brief and to have that brief considered despite its untimeliness (Docket Nos. 60, 62, 63) are granted; Plaintiffs' Motion for Judgment on the Pleadings Pursuant to FRCP 12(c) (Docket Nos. 47, 49) is denied; and Defendant's Motion for Judgment on the Pleadings (Docket No. 52) is granted. The Court finds that amendment of Plaintiffs' claims would be futile and therefore dismisses the TAC without leave to amend. The Court will enter a Judgment consistent with this Order.

IT IS SO ORDERED.

APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED JULY 29, 2020

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

FILED
JULY 29, 2020

FUSION IV PHARMACEUTICALS, INC., DBA AXIA PHARMACEUTICAL, A CALIFORNIA CORPORATION; NAVID VAHEDI, PHARM D.,

Plaintiffs-Appellants,

v.

ANNE SODERGREN, IN HER OFFICIAL CAPACITY AS THE INTERIM EXECUTIVE OFFICER OF THE CALIFORNIA STATE BOARD OF PHARMACY,

Defendant-Appellee,

and

CALIFORNIA STATE BOARD OF PHARMACY; BOARD OF PHARMACY; VIRGINIA HEROLD, EXECUTIVE DIRECTOR, THE CALIFORNIA STATE BOARD OF PHARMACY,

Defendants.

Appendix C

No. 19-55791

D.C. No. 2:19-cv-01127-PA-FFM
Central District of California, Los Angeles

ORDER

Before: RAWLINSON and N.R. SMITH, Circuit Judges, and KORMAN,* District Judge.

Judge Rawlinson has voted to deny the petition for rehearing en banc, and Judge N.R. Smith and Judge Korman have so recommended.

The full court was advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing en banc is DENIED.

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* The Honorable Edward R. Korman, United States District Judge for the Eastern District of New York, sitting by designation.

APPENDIX D — CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution Article I

Section 8.

The Congress shall have power

To regulate commerce with foreign nations, and among the several states, and with the Indian tribes;

U.S. Constitution Article VI

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

§ 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Appendix D

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

§ 353a. Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as

defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with

> the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the ational Association of Boards of Pharmacy, develop a standard memorandum of understanding or use by the States in complying with subparagraph (B)(i).

(c) Advertising and promotion

A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the

compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)

(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) Application

This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(f) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Appendix D

21 U.S. Code § 353b - Outsourcing facilities

(a) In general.

Sections 502(f)(1), 505, and 582 [21 USCS §§ 352(f)(1), 355, and 360eee-1] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting.

The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances.

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)

(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E [21 USCS § 356e] at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk

drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 [21 USCS § 360] (including a foreign establishment that is registered under section 510(i)) [21 USCS § 360(i)]; and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances)

If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective.

The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have

been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug.

The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding.

The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) ELEMENTS TO ASSURE SAFE USE.

In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505-1 [21 USCS § 355-1], or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) PROHIBITION ON WHOLESALING.

The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1) [21 USCS § 353(b)(1)].

(9) FEES.

The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K [21 USCS § 379j-62].

Appendix D

(10) LABELING OF DRUGS.

(A) LABEL.

The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) CONTAINER.

The container from which the individual units of the drug are removed for dispensing or for administration (such

as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information.

The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement.

The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

Appendix D

(b) Registration of outsourcing facilities and reporting of drugs.

(1) Registration of outsourcing facilities.

(A) Annual registration.

Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510 [21 USCS § 360]), and a point of contact email address; and

(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 506E [21 USCS § 356e] during the subsequent calendar year.

Appendix D

(B) Availability of registration for inspection; list.

(i) Registrations.

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

(ii) List.

The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

Appendix D

(2) DRUG REPORTING BY OUTSOURCING FACILITIES.

(A) IN GENERAL.

Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of

individual units produced, and the National Drug Code number of the final product, if assigned.

(B) Form.

Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

(C) Confidentiality.

Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

(3) Electronic registration and reporting.

Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

Appendix D

(4) Risk-based inspection frequency.

(A) In general.

Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 704 [21 USCS § 374]; and

(ii) shall not be eligible for the exemption under section 704(a)(2)(A) [21 USCS § 374(a)(2)(A)].

(B) Risk-based schedule.

The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors.

In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 [21 USCS § 374] within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E [21 USCS § 356e].

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

Appendix D

(5) Adverse event reporting.

Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

(c) Regulations.

(1) In general.

The Secretary shall implement the list described in subsection (a)(6) through regulations.

(2) Advisory committee on compounding.

Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) INTERIM LIST.

(A) IN GENERAL.

Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described [in] such subsection by—

(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

(ii) providing a period of not less than 60 calendar days for comment on the notice; and

(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

(B) SUNSET OF NOTICE.

Any notice provided under subparagraph (A) shall not be effective after the earlier of—

(i) the date that is 5 years after the date of enactment of the Compounding Quality Act [enacted Nov. 27, 2013]; or

(ii) the effective date of the final regulations issued to implement subsection (a)(6).

(4) UPDATES.

The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d) DEFINITIONS.

In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) [21 USCS § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCS § 355], unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E [21 USCS § 356e] at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) [21 USCS § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCS § 355], unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term "approved drug" means a drug that is approved under section 505 [21 USCS § 355] and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(4)

(A) The term "outsourcing facility" means a facility at one geographic location or address that—

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

> **(C)** An outsourcing facility may or may not obtain prescriptions for identified individual patients.
>
> **(5)** The term "sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

(d) [2] OBLIGATION TO PAY FEES.

Payment of the fee under section 744K [21 USCS § 379j-62], as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

§ 371. Regulations and hearings
(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions

of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested

person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by

such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction

of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person

occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) Copies of records of hearings

A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

(h) Guidance documents

(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure

that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

(C)(i) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.

(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance

documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

§ 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

Appendix D

379j–62. Authority to assess and use outsourcing facility fees

(a) Establishment and reinspection fees

(1) In general

For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

(A) an annual establishment fee from each outsourcing facility; and

(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

(2) Multiple reinspections

An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

(b) Establishment and reinspection fee setting

The Secretary shall—

(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

(c) Amount of establishment fee and reinspection fee

(1) In general

For each outsourcing facility in a fiscal year—

(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

(ii) the small business adjustment factor described in paragraph (3); and

(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

(2) Inflation adjustment factor

(A) In general

For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(i) 1;

(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index)

for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

(B) Compounded basis

The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

(3) Small business adjustment factor

The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

(4) Exception for small businesses

(A) In general

In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

(B) Application

To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

(5) Crediting of fees

In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

(d) Use of fees

The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

(e) Supplement not supplant

Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

(f) Crediting and availability of fees

Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.

Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

(g) Collection of fees

(1) Establishment fee

An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 353b(b) of this title for such fiscal year.

(2) Reinspection fee

The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

(3) Effect of failure to pay fees

(A) Registration

An outsourcing facility shall not be considered registered under section 353b(b) of this title in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

(B) Misbranding

All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 352 of this title until the fees owed for such outsourcing facility under this section have been paid.

(4) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31.

Appendix D

(h) Annual report to Congress

Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.

(i) Authorization of appropriations

For fiscal year 2014 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

Cal Bus & Prof Code § 4129

§ 4129. Licensure as outsourcing facility; Adoption of regulations; Review of FDA requirements and guidance documents; Prohibition against providing pharmacy services

(a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the

board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.

(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.

Appendix D

CA Bus & Prof Code § 4129.1 (2017)

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency

inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

CA Bus & Prof Code § 4129.4 (2017)

(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice,

may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.